

REMARKS

Claims 2-12 are pending in the Application. Claims 2-12 have been amended, Claim 1 is herein cancelled. No new matter has been added. Claims 11 and 12 are independent.

Of note, support for the amendments to Claims 11 and 12 can be found in the published Application at Paragraphs [0006], [0008], [0012], [0014], [0034] and elsewhere.

On page 2 of the Office Action, Claims 1-3, 5, 6 and 9-12 are rejected under 35 U.S.C. §102(b) as being anticipated by Dobak, et al., U.S. Patent No. 6,241,722. Claim 1 has been cancelled. In order to anticipate a claim, a reference must disclose each and every element of the claim. Independent Claim 11, as amended, recites a method of preventing postoperative transient arrhythmia, including the steps of “performing a surgical procedure on a heart,” *and* “*postoperatively* cooling selected cardiac *nerves*,” (emphasis added). Similarly, amended independent Claim 12 recites “performing a surgical procedure on a heart,” and “epicardially approaching a selected region of the heart using with a cooling device postoperatively.”

Primarily, Dobak completely fails to include any reference to cooling cardiac nerves, and in fact, fails to include the word ‘nerve’ anywhere in the specification. Rather Dobak ambiguously refers to the treatment of “cardiopulmonary tissue,” and specifically refers to a treatment to “form a lesion in a pulmonary *vein*,” (Col. 17:12-13)(emphasis added) without making any reference or distinction of the inclusion, targeting, or otherwise effecting cardiac nerves. Moreover, the vague reference to “cardiopulmonary tissue” does not necessarily include nerves, and the MPEP sets forth that simply because a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency or likelihood of that result or characteristic.

In addition, Dobak solely refers to a single ablation procedure involving the cooling of 'tissue.' Dobak fails to recite or include any disclosure of "performing a surgical procedure on a heart," such as a bypass procedure, a valve replacement procedure, an incisive Maze procedure or the like, and then "*postoperatively* cooling selected cardiac *nerves*," (emphasis added) as stated in Applicants' independent Claim 11 or "epicardially approaching a selected region of the heart using with a cooling device *postoperatively*," (emphasis added).

With respect to Claim 12, the claimed method includes approaching the selected cardiac nerves "epicardially." The Examiner indicates that Dobak discloses such claimed elements at Col. 7:31-54; Col. 15:64 – Col. 16:45; and Col. 17:8 – Col. 18:3. However, not only do these cited passages of the Dobak reference fail to disclose an epicardial approach, but the entire specification of the Dobak reference refers solely to an endocardial approach through the vasculature and into the heart, as clearly illustrated in FIG. 8.

As Dobak fails to include any disclosure of "cooling selected cardiac nerves," let alone disclosing "performing a surgical procedure on a heart," and "*postoperatively* cooling selected cardiac *nerves*," (emphasis added) or "epicardially approaching a selected region of the heart using with a cooling device *postoperatively*," (emphasis added), Dobak fails to disclose each and every element of Applicants' independent Claims 11 and 12. Furthermore, Dobak fails to disclose or refer to an epicardial approach towards the heart as stated in Applicants' Claim 12. Accordingly, the rejection of amended Claims 11 and 12 under 25 U.S.C. §102(b) is unsupported and a withdrawal of the rejection is respectfully requested. Also, Claims 2-3, 5, 6, and 9-10 are believed to be allowable as they have been amended to depend from amended independent Claim 11.

On page 3 of the Office Action, Claims 1, 2, 4, 7, and 11-12 are rejected under 35 U.S.C. §102(b) as being anticipated by Avitall, U.S. Patent No. 5,733,280. Claim 1 has been cancelled. In order to anticipate a claim, a reference must disclose each and every element of the claim. Primarily, Avitall completely fails to include any reference to cooling cardiac nerves, and in fact, fails to include the word ‘nerve’ anywhere in the specification. Similar to Dobak, Avitall ambiguously refers to the treatment of “tissue” without making any reference or distinction of the inclusion, targeting, or otherwise effecting cardiac nerves. Moreover, the vague reference to “tissue” does not necessarily include nerves, and the MPEP sets forth that simply because a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency or likelihood of that result or characteristic, as stated above.

In addition, Avitall solely refers to a single ablation procedure involving the cooling of ‘tissue.’ Avitall fails to recite or include any disclosure of “performing a surgical procedure on a heart,” such as a bypass procedure, a valve replacement procedure, an incisional Maze procedure or the like, and then “*postoperatively* cooling selected cardiac *nerves*,” (emphasis added) as stated in Applicants’ independent Claim 11 or “epicardially approaching a selected region of the heart using with a cooling device *postoperatively*,” (emphasis added).

As Avitall fails to include any disclosure of “cooling selected cardiac nerves,” let alone disclosing “performing a surgical procedure on a heart,” and “*postoperatively* cooling selected cardiac *nerves*,” (emphasis added) or “epicardially approaching a selected region of the heart using with a cooling device *postoperatively*,” (emphasis added), Avitall fails to disclose each and every element of Applicants’ independent Claims 11 and 12. Accordingly, the rejection of amended Claims 11 and 12 under 35 U.S.C. §102(b) is unsupported and a withdrawal of the

rejection is respectfully requested. Also, Claims 2, 4 and 7 are believed to be allowable as they have been amended to depend from amended independent Claim 11.

On page 4 of the Office Action, Claims 1-3, 6, 8, and 9 are rejected under 35 U.S.C. §102(b) as being anticipated by Webster, Jr., et al., U.S. Patent No. 6,292,695. Claim 1 has been cancelled. Claims 2-3, 6, 8, and 9 are believed to be allowable as they have been amended to depend from independent amended Claim 11.

On page 4 of the Office Action, Claim 4 is rejected under 35 U.S.C. §103(a) as being unpatentable over Dobak, et al. ('722). Claim 4 is believed to be allowable as it depends from amended Independent Claim 11.

For all of the above reasons, the claim objections are believed to have been overcome placing Claims 2-12 in condition for allowance, and reconsideration and allowance thereof is respectfully requested.

The Examiner is encouraged to telephone the undersigned to discuss any matter that would expedite allowance of the present application.

The Commissioner is hereby authorized to credit overpayments or charge payment of any additional fees associated with this communication to Deposit Account No. 502104.

Respectfully submitted,

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